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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,682	01/10/2001	Fahri Saatcioglu	586.02-US1	6146

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[REDACTED] EXAMINER

RAWLINGS, STEPHEN L

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1642

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/743,682	SAATCIOGLU, FAHRI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 October 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 27-36 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-36 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                            |                                                                             |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. The election without traverse filed October 15, 2002 in Paper No. 10 is acknowledged and has been entered.
2. Claims 1-36 are pending in the application. Claims 1-20 and 27-36 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.
3. Claims 21-36, insofar as the claims are drawn to the elected invention, are currently under prosecution.

***Specification***

4. The use of the numerous trademarks has been noted in this application. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., <sup>TM</sup>, ®), and accompanied by generic terminology.

An example of an improperly demarcated trademark appears on page 8 in line 2, namely Qiagen<sup>TM</sup>. Applicant is required to identify and correct others.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

5. This application does not contain an abstract of the disclosure as required by 37 CFR § 1.72(b). An abstract on a separate sheet is required.
6. The disclosure is objected to because of the following informalities:

"Qiagen™" is misspelled on page 8 in line 2. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for detecting a neoplastic cell. The claimed method comprises detecting and measuring the level of an intracellular protein in a cell-containing system and correlating the quantity of the protein with the presence of a neoplastic cell in the system. The intracellular protein to which the claims refer must comprise SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14.

The teachings of the specification cannot be extrapolated to the enablement of the claimed invention because the amount of guidance, direction, and exemplification set forth in the specification are insufficient to enable the skilled artisan to have a reasonable expectation of successfully using the claimed invention to detect a neoplastic cell without having the need to perform additional, undue experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The specification teaches that the polypeptides of SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 are the translation products of an alternatively spliced messenger RNA (mRNA) molecule. The specification teaches that SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 are encoded by SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 6, respectively. The specification teaches that SEQ ID NO: 3 comprises SEQ ID NO: 2, but SEQ ID NO: 2 does not comprise SEQ ID NO: 3; SEQ ID NO: 6 comprises neither SEQ ID NO: 2 or SEQ ID NO: 3, and neither SEQ ID NO: 2 nor SEQ ID NO: 3 comprise SEQ ID NO: 6. Accordingly, it is expected that the polypeptide of SEQ ID NO: 11 comprises SEQ ID NO: 10, but the polypeptide of SEQ ID NO: 10 is not expected to comprise SEQ ID NO: 11. The polypeptides of SEQ ID NO: 10 and SEQ ID NO: 11 are not expected to comprise SEQ ID NO: 14; and the polypeptide of SEQ ID NO: 14 is not expected to comprise either SEQ ID NO: 10 or SEQ ID NO: 11. In fact, there is no factual evidence set forth in the specification that a polypeptide comprising SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 exists in a neoplastic cell, or for that matter any other cell.

The teachings of the specification therefore cannot be extrapolated to the enablement of the claimed invention because one skilled in the art cannot predict whether a polypeptide comprising SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 exists in a neoplastic cell, or any other cell, and cannot predict whether a particular predetermined amount of the polypeptide, if present in a cell of the system will correlate with the presence of neoplastic cell in the system. Applicant proposes to detect the presence of a neoplastic cell in a system, e.g., a biopsy, by a process that comprises detecting a polypeptide encoded by an alternatively spliced mRNA molecule that has not been shown to exist. The skilled artisan could not have a reasonable expectation of successfully practicing the claimed invention without at least first determining whether the polypeptide is expressed in neoplastic cells, a feat that would require additional, undue experimentation. To have a reasonable expectation of success, the practitioner would further need to determine what amount of the polypeptide correlates with the presence of a neoplastic cell in the system.

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Because the skilled artisan could not have a reasonable expectation of successfully practicing the claimed invention to detect a neoplastic cell in a system, even given the benefit of Applicant's disclosure, without needing to perform additional, undue experimentation, the disclosure is insufficient to meet the requirements set forth under 35 USC § 112, first paragraph.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-26 are indefinite because claim 21 does not recite a positive process step that clearly relates back to the preamble of the claim. Due to the lack of a positive process step that clearly relates back to the preamble of the claim, it cannot be ascertained whether each and every step that Applicant regards as essential to the successful practice of the claimed invention and more particularly, to the achievement of the objective stated in the preamble of the claim is recited in the body of the claim. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Claims 21-26 are indefinite because claim 21 recites the term "a predetermined quantity of an intracellular polypeptide". Recitation of the term renders the claim indefinite because it cannot be determined how the claim requires the quantity of the polypeptide be predetermined. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 21-26 are vague and indefinite because claim 21 recites the step of "correlating a predetermined quantity of an intracellular polypeptide [...] with a presence of a neoplastic cell". Recitation of the step renders the claim vague and indefinite

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because it is unclear how the claim requires the quantity of the polypeptide and the presence of a neoplastic cell to correlate.

***Conclusion***

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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slr

January 2, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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